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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,951	11/27/2000	Charles E. Weeks	HOLISED.033A	6317

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/16/2002 11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,951	WEEKS, CHARLES E.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 22-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 22-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-11 and 22-38 are pending.

The amendments of claims 1-11 filed April 9, 2002 has been entered. The cancellations of claims 12-21 filed April 9, 2002 is acknowledged. The addition of claims 22-38 filed April 9, 2002 is acknowledged.

Newly submitted claims 33-38 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inflammation is condition that encompassed more than arthritis such as asthma, inflammatory bowel diseases. Those diseases are routinely treated by vastly different agents that are not interchangeable. For example, asthma can be treated with β-blockers and bronchodialators such as theophylline; inflammatory bowel diseases can be treated with 5-ASA.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-38 (in part) are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-11 and 22-38 will be examined to the extent they read on elected invention.

All claims are examined insofar as they read on the **treatment** of arthritis.

The outstanding rejections under 35 USC 112, first paragraph have been withdrawn in view of the amendments filed April 9, 2002.

The outstanding rejections under 35 USC 112, second paragraph in regard to "appreciably metabolized" in claim 1 and 12 have been withdrawn in view of the amendments filed April 9, 2002.

The outstanding rejections under 35 USC 102(b) have been withdrawn in view of the amendments filed April 9, 2002.

Claim Objections

Claims 22 –30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "tissue inflammation" in claim 22 fails to further limit the method recited in claim 1 or 2. The method of claims 22 is directed a method of treating arthritis, i.e., the inflammation of the joint. "tissue inflammation" as recited in claim 22 encompasses inflammatory sites other than joints and thus, failing to further limit the preceding claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 11, 26, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "patient afflicted with arthritis-related tissue inflammation" in claims 7 and 26 renders the claims indefinite as to what patients are encompassed by the claims. It is not clear what tissue inflammation conditions are encompassed by the expression herein and therefore, it is not clear which patient populations are encompassed thereby.

The expression "patient diagnosed with arthritis-related tissue inflammation" in claims 11 and 30 renders the claims indefinite as to what patients are encompassed by the claims. It is not clear what tissue inflammation conditions are encompassed by the expression herein and therefore, it is not clear which patient populations are encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lardy (US Patent 5,585,371) in view of Peat (US Patent 4,628,052), references of record in the previous office action mailed December 5, 2001.

Lardy teaches that Δ5-androstene-3β-ol-7, 17-dione (7-oxo-DHEA), a DHEA derivative only differs by the C_7 substituent, has a similar immunological activity with DHEA (See the abstract and Example V).

Lardy does not expressly teach that 7-oxo-DHEA is useful in a method to treat arthritis such as osteoarthritis, fibromyalgia, and rheumatoid arthritis.

Peat teaches that DHEA is useful in a method of osteoarthritis, rheumatoid arthritis, and non-specific joint pain (see particularly abstract).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to employ 7-oxo-DHEA in the method of Peat treat arthritis such as osteoarthritis, fibromyalgia, and rheumatoid arthritis.

One of ordinary skill in the art would have been motivated to employ 7-oxo-DHEA in the method of Peat treat arthritis such as osteoarthritis, fibromyalgia, and rheumatoid arthritis. It is known that both DHEA and 7-oxo-DHEA have similar immunological effect and based on Lardy, DHEA is known to be useful in method of treating painful condition of osteoarthritis and rheumatoid arthritis. Employing 7-oxo-DHEA, a structurally similar compound and also has the similar pharmacological activities as DHEA, in the same method of Peat to treat arthritis such as osteoarthritis, rheumatoid arthritis and would have been reasonably expected to be similarly effective. Since the method of Peat can treat non-specific joint pains, therefore employing 7-oxo-DHEA, a structurally similar compound and also has the similar pharmacological activities as DHEA, in the method of treating fibromyalgia, which commonly accompanied by joint pain, would have been reasonably expected to be similarly effective.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In this case, there is no data in the instant specification for evaluation of unexpected benefits. Therefore, no clear and convincing evidence for the unexpected benefits are seen herein.

Response to Arguments

Applicant's rebuttal arguments filed April 2, 2002 regarding DHEA and 7-oxo-DHEA not having similar immunological effect have been fully considered but they are not persuasive. Both compounds can enhance immunological system, in a different degree, not in a different manner. Therefore, both compounds are still considered as having similar immunological effect, which is enhancing the immunological system.

Applicant's rebuttal arguments filed April 2, 2002 regarding the instant specification disclosing the different pharmacological properties of DHEA and 7-oxo-DHEA have been considered but are not found persuasive. As discussed in the obviousness rejection, it is the applicant's burden to illustrate with evidence for unexpected results: in this case, the pharmacological differences of DHEA and 7-oxo-

DHEA. Absent evidence of unexpected results, the cited prior art still renders the claims.

Applicant's rebuttal arguments filed April 2, 2002 averring the cited prior art teaching the immunological activities of DHEA and 7-oxo-DHEA would exacerbate, not treat, arthritis and related inflammatory conditions have been considered but are not found persuasive. As discussed above, DHEA and 7-oxo-DHEA have similar immunological effect and structure. Therefore, one of ordinary skill in the art would reasonably expect that 7-oxo-DHEA be useful in treating arthritis. Please note that DHEA would also enhance immunological activities and it is useful in treating, not exacerbating, arthritis.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

San-ming Hui
July 15, 2002